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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/467,076	12/20/1999	JOSE CIBELLI	000270-088	1896

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EXAMINER

WOITACH, JOSEPH T

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 06/20/2002

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/467,076

Applicant(s)

CIBELLI ET AL.

Examiner

Joseph Weitach

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 April 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

This application filed December 20, 1999 which claims benefit to PCT/US99/04608, filed March 2, 1999, which claims priority to 08/699,040, filed August 19, 1996, and is a continuation in part of 09/395,368, filed September 14, 1999, now abandoned, which is a continuation in part of 09/260,468, filed March 2, 1999, which are a continuation in part of 09/032,945, filed March 2, 1998, now abandoned, which is a continuation in part of 08/699,040, filed August 19, 1996.

Applicants' amendment filed April 2, 2002, paper number 10, has been received and entered. The specification has been amended. The drawings have been added. Claim 35 has been canceled. Claims 1, 2, 27-32, 36 and 50 have been amended. Claims 55-58 have been added. Claims 1-34 and 36-58 are pending and currently under examination.

Note that claim 27 has been amended to recite 'Human [E]mbryonic [or] stem-like cells obtained...' and that the previous claim simply recited 'Embryonic or stem-like cell'. The marked-up version did not indicate that "Human" was intentionally introduced because it was not underlined. Claim 27 has been amended as recited in the clean copy of the claims, however this is noted for Applicants convenience because this significantly narrows the scope of the claim.

Oath/Declaration

The supplemental declaration filed April 2, 2002, attachment to paper number 10, is in compliance with 37 CFR 1.67(a).

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Specification

The objection to the specification because the reference to related applications should be updated to reflect the status of the applications is maintained. It is noted that the declaration filed with the present disclosure claims priority to applications which are not listed in the first line of the specification. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)).

Appropriate correction is required.

Claim Objections

Claims 27-33 and 57 are objected to because of the following informalities: the claims should begin with an article such as "A", "The", etc. See MPEP § 608.01(m).

Appropriate correction is required

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 27-32 rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn.

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The amendments to the claims have obviated the basis of the rejection. Specifically, in light of the amendment to the claims to encompass 'embryonic stem like cells', Examiner agrees that the instant claims are not directed to non-statutory subject matter. Therefore, the rejection is withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-34, 36-54 stand rejected and newly added claims 55-58 are under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants summarize the basis of the rejection, noting amendments to the claims to more clearly set forth 'embryonic stem-like cell' and that said cells comprise the nucleus from a first species and the mitochondria from an oocyte of a second different species. Applicants note that the instantly claimed cells and methods of making are distinguished from those disclosed in the prior art because the cells contain xenogeneic mitochondria. Applicants note that the instantly claimed method is possible as evidenced by recent data gathered by the present inventors. Specifically, the evidence demonstrates that a gaur has been cloned by inserting the

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nuclear material of a somatic cell of a gaur into an enucleated oocyte of a bovine. Given that a live calf is produced containing gaur nuclear material and bovine mitochondria, Applicants argue that embryonic and/or stem-like cells which differentiated into a mammal are thus produced by the instantly claimed method. Applicants note that the production of an animal is not the only utility of the instantly claimed method and cells produced by said method, emphasizing other utilities for embryonic stem cells set forth in the present specification. Finally, Applicants point out that once embryonic cells are obtained, methods known and used in the art for existing embryonic stem cells can easily be extended to the cells instantly claimed or produced by the instantly claimed method. See Applicants' amendment, pages 8-11. Applicants' arguments have been fully considered, but not found persuasive.

For clarity of the record, it is noted that 'species' is not specifically defined in the present specification, and that it is being interpreted as the biological division between the genus wherein the individuals of a species generally bear close resemblance to one another and breed effectively to produce fertile progeny (see Stedman's dictionary, page 1642). This particular definition is figuratively supported throughout the specification and in Applicants' arguments describing the nature of the cell as xenogeneic. Additionally, it is noted that the bovine and gaur (*Bos taurus* and *Bos gaurus*, respectively) used in the post filing evidence are both from the same species *Bos*.

The amended claims are directed to a method for the production of embryonic stem-like cells, and more specifically human ES cells, wherein the resulting cells contain the nuclear

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material of a first species and the mitochondria of a second different species. Examiner would concede that once embryonic cells are made, that the genetic alteration of said cells may be accomplished by methods known and used in the art for existing embryonic cells. It is noted that at the effective filing date of the instant application, that the instantly claimed cells were not described or characterized and thus, there was no specific evidence that embryonic cells from any source could not be manipulated by methods known in the art at the time of filing. However, at the time of the filing of the instant specification, Cibelli *et al.* (Nature Biotechnology 16:642-46), 1998) clearly teach that because of the nature of the resulting chimeric ES cells, the ES cells themselves have limited use in known gene targeting methodology (see page 644, top of second column). Additionally, because germline transmission was not demonstrated, the cells described by Cibelli *et al.* were referred to “as 'pluripotent or ES-like cells' instead of ES cells” (*ibid*). Even if one were to acquiesce that the term ES cells as used in the art encompasses both pluripotent and totipotent cells, the basis of the present rejection focuses on the failure of the present specification to enable the instantly claimed methods and consequently, the cells produced from said method and any further method steps using said cells. More specifically, Examiner would concede that the specific method steps recited in the presently claimed methods are fully enabled as reflected by nuclear transfer technology known and used in the art. However, the basis of the rejection focuses on the ability of the method steps to result in a chimeric embryonic stem-like cell.

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As noted in the previous office action, the specification discloses the preparation of nuclear transfer units using a method of nuclear transfer of adult human epithelial cell nuclei into enucleated bovine oocyte to form a nuclear transfer (NT) unit by electrofusion techniques. The method disclosed in Example 1 of the specification result in the production of a NT unit (16-400 cell stage) according to Table 1, page 64. Although the methods of the instant invention result in the production of a NT unit of which Applicants report propagates into what appears to be ES-like cell colonies (as determined by cell morphology); the specification fails to demonstrate that the ES-like cells function as true ES-cells in that they function as stem cells in that are capable of differentiation into other multilineage cell-types. As such, Applicants fail to enable the production of embryonic or stem-like cells as recited in step (v).

The specification teaches that the prior art is lacking in the production of inner cell mass cells from NT units useful to form ES cell-like colonies that could be propagated (page 7, lines 10-13). Thus, the artisan could only rely on the instant specification. It is noted that the specification does not provided evidence that the cells produced by their methods are true pluripotent cells (embryonic stem cells or embryonic stem-like cells) failing to demonstrate whether their ES-like cells stain positive for alkaline phosphatase (AP), exhibit the formation of embryoid bodies, spontaneously differentiate into at least two different cell type, or express ES cell markers, only disclosing several morphological characteristics (Example I, page 62).

In light of the evidence provided in the inventors post-filing articles, Examiner would agree that nuclear transfer using the oocyte and nuclear material from subspecies of animals

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would be fully enabled. Similar to the results presented in the Inventors work, Meirelles *et al.* (Genetics 158:351-356, 2001) demonstrate that methods of nuclear transfer where the nuclear material of *Bos indicus* is inserted into the oocyte of *Bos taurus* produces calves comprising the nuclear material of *Bos indicus* and the mitochondria of *Bos taurus*. Meirelles *et al.* teach that previous attempts to use the *Bos* oocyte as hosts for nuclear transfer from unrelated species allowed development to the blastocyst stage, however conclude that incompatibility among the nuclear and mitochondrial genetic systems is responsible for the early arrest. Meirelles *et al.* also point to similar failures using *Mus caroli* and *Mus musculus* citing Dominko *et al.* discussed in length in the previous office action. Meirelles *et al.* conclude that in light of their results and the failures of the prior art, that nuclear transfer across subspecies barriers is possible. Early experiments demonstrate that the methodology of nuclear transfer can be performed, however the cells resulting from cross species nuclear transfer demonstrate dramatically decreased proliferation capacity the greater the phylogenetic distance, and have been incapable of fully developing/proliferating (see for example Prather *et al.* (J Reprod Fertil Suppl 41:125-34, 1990)). A review of the art clearly indicates that the successful use of nuclear transfer methodology occurred when the nuclear material and the host oocyte were from the same species. It is noted that the specification must teach those of skill in the art how to make and how to use the invention as broadly claimed. *In re Goodman*, 29 USPQ2d at 2013 (Fed. Cir. 1994), citing *In re Vaeck*, 20 USPQ2d at 1445 (Fed. Cir. 1991). Furthermore, the Federal Circuit has stated that:

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a specification need not disclose what is well known in the art. See, e.g., *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986). However, that general, oft-repeated statement is merely a rule of supplementation, not a substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement.

However, when there is no disclosure of any specific starting material or of any of the conditions under which a process can be carried out, undue experimentation is required; there is a failure to meet the enablement requirement that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art. It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement.

Genentech Inc. v. Novo Nordisk A/S, 42 USPQ2d 1005 (CAFC 1997) (emphasis added).

The specification provides for nuclear transfer methodology which is well known in the art, however the specification fails to provide guidance to the skilled artisan on any parameters which would be necessary and critical for the production of human or mammalian embryonic stem-like cells by the cross-species NT process which exhibit embryonic stem cell properties or even mere differentiation upon induction.

Thus, in view of the lack of guidance, working examples, breadth of the claims, the level of skill in the art and state of the art at the time of the claimed invention was made, it would have required one of skill in the art undue experimentation to practice the invention as claimed. Therefore, for the reasons above and of record, the rejection is maintained.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 50-54 stand rejected and newly amended claims 1-34, 36-49 and 55-58 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

First, it is noted that amendments to the claims has obviated the basis of the specific rejections previously set forth for claims 1-49.

Claim 50 has been amended to recite that 'a detectable marker, the expression of which is operably linked to the expression of a particular cyclin', however it is maintained that the claim is vague and unclear. Applicants argue that the meaning of the phrase is clear in light of the teachings of the disclosure, pointing to page 49. Examiner would agree that the teachings on page 49 are clear, however the claim does not reflect the specific teaching set forth on this page of the specification. The instant claim is unclear because how the expression of the marker is operably linked is not clearly set forth. It is unclear if the expression of a cyclin itself would infringe on the claim or if any gene that is regulated by a cyclin is encompassed by the claim. More clearly setting forth that the detectable marker is operably linked to a cyclin promoter to reflect the teaching on page 49 would obviate the basis of the rejection. Dependent

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claims 51-54 are included in this rejection because they fail to clarify the basis of the rejection.

Claims 1-34, 36-49 and 55-58 are vague, unclear and confusing because while the preamble indicates that the method is used for producing ES cells with the mitochondria of one species and the nuclear material of second different species, the final step simply recites isolating cells. There is no indication in the final step that the cells isolated are chimeric and meet the limitation recited in the preamble. Further, dependent claims are confusing because they recite further method steps wherein mitochondria of the same species as that of the nuclear material is introduced into the ES cell. This is confusing because this is counter to intent of the method which is to provide and result in the presence of the mitochondria of second different species. In view of the teachings in the present specification and the art of record, using nuclear transfer methodology results in only mtDNA homoplasmy. Further, the initial presence of two sources of mtDNA, heteroplasmy, still results in cells which are homogeneous for one mtDNA, and the process appears random without some potential sort of selection. The claims are unclear because it appears that the cells isolated in the final step of claim 1(vi) can be both chimeric and normal. Further, the claims are confusing because further method steps are recited which are contrary to the intent of the method. Clearly indicating in the final step that the cells which are isolated have the nuclear material of one species and the mitochondria of a second different species,

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and that further method steps do not alter this outcome would obviate the basis of the rejection. Dependent method claims and product claims are included in the basis of the rejection because they do not further clarify the basis of the rejection, and it is unclear if the instantly claimed cells would also encompass normal, *i.e.* non-chimeric, ES cells.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim 27 rejected under 35 U.S.C. 102(b) as being anticipated by Bradley *et al.*

(Biotechnology, 1992) is withdrawn.

The amendment to claim 27 to recite human embryonic stem-like cell has differentiated the cell from the mouse ES cell taught in Bradley *et al.*

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Claims 27-32 stand rejected under 35 U.S.C. 102(a) as being anticipated by Granerus *et al.* (Cell Proliferation, 1996).

Claims 27-34 and 50-54 stand rejected under 35 U.S.C. 102(e) as being anticipated by Tsukamoto *et al.* (US Patent 5,716,827).

Claims 27-34 and 50-54 stand rejected under 35 U.S.C. 102(b) as being anticipated by Yamane (Japanese Journal of Cancer and Chemotherapy, 1987).

The claims as amended are directed to human embryonic stem-like cells. Applicants argue that the claims as amended have differentiated the cells instantly claimed from those taught in either Granerus *et al.*, Tsukamoto *et al.* or Yamane. See Applicants amendment, pages 14-15. Applicants' arguments have been fully considered, but not found persuasive.

Examiner would agree that neither Granerus *et al.*, Tsukamoto *et al.* nor Yamane teach chimeric embryonic stem-like cells, however as noted in the previous office action, the patentability of a product-by-process claim is determined by the novelty and nonobviousness of the claimed product itself without consideration of the process for making it which is recited in the claims. *In re Thorpe*, 227 USPQ 964 (Fed. Cir. 1985). In light of the teaching of the present specification and the art of record, the cells resulting from practicing nuclear transfer methodology can result in cells having the mtDNA of the donor nuclear material. Because the final step of the claimed methods does not specifically exclude the isolation or presence of non-

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chimeric cells, the human embryonic stem-like cells taught by Granerus *et al.*, Tsukamoto *et al.* and Yamane anticipate the claims. Amending the method claims to result in a cell comprising the mtDNA from one species and the nuclear material of second different species would obviate this rejection.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

Claims 27-34, 36 and 50-54 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Tsukamoto *et al.* (US Patent 5,716,827).

As noted above the claims as amended are directed to human embryonic stem-like cells. Applicants argue that the claims as amended have differentiated the

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cells instantly claimed from those taught in Tsukamoto *et al.* See Applicants amendment, page 15. Applicants' arguments have been fully considered, but not found persuasive.

As argued above Examiner would agree that Tsukamoto *et al.* does not teach chimeric embryonic stem-like cells, however as noted in the previous office action, the patentability of a product-by-process claim is determined by the novelty and nonobviousness of the claimed product itself without consideration of the process for making it which is recited in the claims. *In re Thorpe*, 227 USPQ 964 (Fed. Cir. 1985). In light of the teaching of the present specification and the art of record, the cells resulting from practicing nuclear transfer methodology can result in cells having the mtDNA of the donor nuclear material. Because the final step of the claimed methods does not specifically exclude the isolation or presence of non-chimeric cells, the human embryonic stem-like cells taught by Tsukamoto *et al.* anticipate the claims. Amending the method claims to result in a cell comprising the mtDNA from one species and the nuclear material of second different species would obviate this rejection.

Thus, the claimed invention, as a whole, was clearly *prima facie* obvious in the absence of evidence to the contrary, and the rejection is maintained.

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Claims 1-34 and 50-54 rejected under 35 U.S.C. 103(a) as being unpatentable over Wolfe *et al.* (Theriogenology, 1990), Collas *et al.* (Molecular Reproduction and Development, 1994) and Westhusian *et al.* (Theriogenology, 1996) is withdrawn.

Applicants argue that none of the references specifically teach the use of cross-species nuclear transfer for the development of chimeric embryonic stem-like cells. Further, in view of the teachings in the art at the time of filing indicating the unpredictability of the art, one of skill in the art would not be motivated to combine the cited references. See Applicants amendment, pages 15-16. Applicants' arguments have been fully considered, and found persuasive.

Examiner agrees that in view of the unpredictability and failures of the art, there would not have been a reasonable expectation of success to successfully. It is noted that consistent with the rule that all evidence of nonobviousness must be considered when assessing patentability, the PTO must consider comparative data in the specification in determining whether the claimed invention provides unexpected results. *In re Margolis*, 785 F.2d 1029, 1031, 228 USPQ 940, 941-42 (Fed. Cir. 1986). However, "[i]t is well settled that unexpected results must be established by factual evidence. Mere argument or conclusory statements in the specification does not suffice." *In re De Blauwe*, 736 F.2d 699, 705, 222 USPQ 191, 196 (Fed. Cir. 1984); see also *In re Wood*, 582 F.2d 638, 642, 199 USPQ 137, 140 (CCPA 1978) ("Mere lawyer's arguments and conclusory statements in the specification,

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unsupported by objective evidence, are insufficient to establish unexpected results.");

In re Lindner , 457 F.2d 506, 508, 173 USPQ 356, 358 (CCPA 1972) (" [M]ere conclusory statements in the specification . . . are entitled to little weight when the Patent Office questions the efficacy of those statements.") and *In re Dill*, 604 F.2d 1356, 1361, 202 USPQ 805, 808 (CCPA 1979) ("The evidence presented to rebut a prima facie case of obviousness must be commensurate in scope with the claims to which it pertains."). Further, in applications directed to inventions in arts where the results are unpredictable, the disclosure of a single species usually does not provide an adequate basis to support generic claims. *In re Soll*, 97 F.2d 623, 38 USPQ 189 (CCPA 1938). In cases involving unpredictable factors, such as most chemical reactions and physiological activity, more may be required. *In re Fisher*, 166 USPQ 18 (CCPA 1970) (contrasting mechanical and electrical elements with chemical reactions and physiological activity). See also *In re Wright*, 999 F.2d 1557, 27 USPQ2d 1510 (Fed. Cir. 1993); *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). This is because it is not obvious from the disclosure of one species, what other species will work. *In re Dreshfield*, 110 F.2d 235, 45 USPQ 36 (CCPA 1940), gives this general rule: "It is well settled that in cases involving chemicals and chemical compounds, which differ radically in their properties it must appear in an applicant's specification either by the enumeration of a sufficient number of the

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members of a group or by other appropriate language, that the chemicals or chemical combinations included in the claims are capable of accomplishing the desired result."

Conclusion

No claim is allowed. Claims 1-26, 37-49 and 55-58 are free of the art of record, however they are subject to other rejections.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist Pauline Farrier whose telephone number is (703)305-3550.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

Joseph T. Woitach

Deborah Crouch
DEBORAH CROUCH
PRIMARY EXAMINER
GROUP 1800/630